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PAUL DOMB
Vice President
Asset Management

August 9, 2004

Division of Dockets Management
(HFA – 305)
FDA
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Dear Sir or Madam:

The enclosed is to be submitted to each member of the Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Advisory Committee on September 13th and September 14th, Docket No. 2004N-0330.

I also request the enclosed statement be on the record. Should you have any questions, please contact me at (305)358-7711. Thank you.

Sincerely,

Paul M. Domb

PMD:ddb
Enclosure

2004N-0330

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To the Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Advisory Committee.

Frankly, it is difficult to draft this letter with the composure necessary to maintain its legitimacy. The good faith, innocence and hope that characterized my early communications with this office have diminished; in the wake of the FDA's unpardonable oversights and deliberate obfuscations regarding the dangers of SSRI's, I simply wish to report that I, and many others, are, at the very least, on to the carefully orchestrated hoax, which is anything but funny. Ultimately, I am ashamed of the FDA's behavior, and to the extent a conscience exists behind office titles, you should be equally embarrassed.

Prior to the last meeting on February 2, 2004, I submitted (via Anuja Patel) a letter to each committee member summarizing my experience with Paxil. It set forth numerous details, including: a) my direct correspondence with Glaxo; b) the fact that Glaxo's Head of Neuroscience (Dr. Raj Kumar) told me they are "doling out Paxil like candy;" c) my years of sober correspondence with Dr. Janet Woodcock during which time I tried to bring her attention to the real suicide dangers surrounding Paxil; d) the fact that FDA criminal investigators came to my office, but when I pressed them for information, I was told the Paxil documents were under "protective order;" e) documented proof obtained through the Freedom of Information office and correspondence with experts in pharmacology and academic institutions throughout the world highlighting Paxil's maverick science and misleading factual reporting. Finally, in this same memo, I also quoted Dr. Woodcock's claim that the "FDA is on top of these issues and is pursuing carefully, scientifically based analysis."

I am curious: did anyone read this memo? Or was it, like so much else, simply ignored during your careful analysis?

The FDA seems content to rely on "scientific data" which amounts to clinical research trials in which the clinicians are subsidized by Glaxo to present favorable outcomes on their "wonder drug." But nearly all of the panelists knew and know that the playing field between Glaxo and the FDA was never level for consumers. The deck, as you well know is stacked so heavily in favor of Glaxo and other pharmaceutical companies, that if the ramifications of the Paxil menace were not so serious, the situation would be otherwise comical. Many like myself have watched astounded as the FDA acted as an institutional (and well-lobbied) rubber stamp for "remedies" tainted by supply and demand rather than honored by objective science. As opposed to protecting consumers, the FDA has endangered them in a role nothing shy of the fox guarding the hen house. Again, and with the calmest voice possible: shame on you.

In February's meeting, you heard repeated pleas from parents whose children committed suicide. They came from all walks of life. Their pleas, however, were for you to warn parents, doctors and consumers that the risk of suicide in Paxil and other SSRI's is real and not merely an excuse used by the guilt-ridden survivors of predisposed suicidal kids. From expert to parent, the message was clear: the problem in the majority of cases was not the patient, it was Paxil. They begged you to envision and consider the deaths of their children so that others might live. They asked that this experienced panel with revered academic credentials do something. What have you done?

Speakers came from all over the United States to tell family tragedies about SSRI's and had a mere two minutes to speak before their microphone was callously shut off. To make matters worse, you withheld from the proceedings Dr. Mosholder's findings and when his findings were leaked to the press, the FDA (more concerned about an internal leak than the important issue of the suicide consequences of SSRI ingestion) took immediate action to determine the source of the leak. Such immediate action would have been better put to use in preventing the needless deaths of those children no longer here to write letters like this one. The FDA behaved like Nero who literally fiddled around as Rome burned.

I offered my contact information, my address and phone numbers to the 40+/- committee members on February 2nd. I was also in attendance and do you know how many in your panel asked me what I knew, how I knew it or in what manner I could help? ...Not one phone call, e-mail or letter. Silence from all of you. Does one need a PhD to be heard, or will the truth suffice?

These are matters that can't be taught in graduate school. Right from wrong is learned at an early age, about the same age many of these Paxil users died.

Truth be told, I believe, despite the corruption which permeates and surrounds the pharmaceutical industry, the issue of SSRIs anti-depressants and suicide will one day be looked back on as the turning point that brought reform to a system out of control.

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